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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,979	02/12/2001	Parula Mehta	98,375-C	1569

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EXAMINER
BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,979	Applicant(s) MEHTA ET AL.	
	Examin r Brenda G. Brumback	Art Unit 1642	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9 are pending and examined on the merits.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112/101

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 recite a first and second solution which when combined comprise an unstable staining solution (step a in each of the claims). "Comprise" is interpreted as open claim language and allows for the presence of other components in the unstable solution. It is unclear how two solutions combined could form a composition which contains components additional to the first and second solutions. It is suggested that applicant amend the claim to recite something such as "wherein the at least first and second stable solutions form an unstable solution when combined" or other appropriate language.

Claim 1 provides for the use of an automated delivery system (step d) but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a

claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 3 is indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h)).

Claim 3 recites cell components including organelles, chromosomes, etc. The claim is indefinite because it the specification fails to disclose what is encompassed within the definition of cell components. Are cell components limited to those recited in the claim, or are other (undisclosed) components also encompassed. Similarly, the claim is indefinite for recitation of microorganisms including parasites, viruses, bacteria, and fungi, as it is unclear if the term "microorganisms" encompasses other undisclosed species. Absent such disclosure, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite. Additionally, the metes and bounds of "other body fluids, excretions, and secretions" are unclear.

Claim 4 is indefinite for recitation of fungi staining solutions because the specification fails to teach the particular solutions which are encompassed. Additionally, the claims recite silver staining solutions, iron staining solutions, iron hematoxylin solutions, trichrome staining solutions, mucin stains, mucicarmine staining solutions, and amyloid staining solutions in the plural. The claim is indefinite because it is unclear if these terms each refer to a single species of if multiple species are encompassed; if multiple species are encompassed, the specification fails to teach what specific species are encompassed. Absent this teaching, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. (U.S. Patent 3,431,886) in view of Copeland et al. (U.S. Patent 5,650,327).

For purposes of examination, the claimed invention has been interpreted as drawn to an automated method for staining biological materials on a slide, selected from tissue sections and cellular components among others, comprising providing at least first and second staining solutions, providing a slide with a biological material to be stained present on the slide, providing an automated delivery system to deliver a predetermined quantity of the first and second staining solutions to the biological material on the slide, sequentially applying the at least first and second staining solutions to the biological material and mixing the first and second staining solutions on the biological material, wherein the step of mixing includes applying a gas stream or at least two gas streams to form a vortex.

McCormick et al. teach an automated method for staining biological materials on a slide comprising providing a plurality of staining solutions (see column 2, lines 6-17), providing a slide having biological materials such as tissue sections or cells placed thereon (see column 1, lines 36-45), providing an automated delivery system to deliver a predetermined amount of the staining solutions to the slide, and sequentially applying the staining solutions to the slide (see column 2, lines 18-40). McCormick et al. teach application of reagents that satin particular portions or components of a cell (see column 1, lines 51-55). McCormick et al. do not teach mixing the reagents on the slide by applying at least two gas streams to form a vortex, as in the present invention.

Copeland et al. teach an automated method for staining tissue sections mounted on slides (see column 1, lines 15-20) comprising applying a reagent staining solution to the slide and mixing the solution on the surface of the slide containing the tissue by applying a gas stream or two gas streams so as to form a vortex (see column 4, lines 35-50).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have mixed the reagents in the automated staining method disclosed by McCormick et al. according to the procedure taught by Copeland et al. in order to facilitate uniformity of staining and eliminate the requirement for a separate reagent mixing step prior to staining of the slides.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. in view of Copeland et al. and McManus et al. (Staining Methods, Histologic and Histochemical, Paul B. Hoeber, Inc., New York, 1960).

The claimed invention is drawn to an automated method for staining biological materials on a slide, selected from tissue sections and cellular components among others, comprising providing at least first and second stable stock solutions which become unstable upon mixing, providing a slide with a biological material to be stained present on the slide, providing an automated delivery system to deliver a predetermined quantity of the first and second stable stock solutions to the biological material on the slide, sequentially applying the at least first and second stable solutions to the biological material and mixing the first and second stable solutions on the biological material so as to form a working or unstable staining solution, wherein the step of mixing includes applying a gas stream or at least two gas streams to form a vortex. Dependent claims 6-9 recite the further limitations of specific staining reagents.

McCormick et al. in view of Copeland et al. teach an automated method for staining biological materials on a slide comprising sequentially applying a plurality of staining solutions onto the surface of a slide containing a tissue section or cellular material. McCormick et al. do not teach forming the unstable

or working staining solution directly on the slide by applying one or more gas streams, as in the present method, and do not teach the specifically recited staining reagents of claims 6-9.

Copeland et al. teach an automated method for staining biological material on a slide comprising applying a plurality of staining reagents and mixing the solutions on the surface of the slide by applying one or two gas streams to the surface of the slide so as to form a vortex.

McMannus et al. teach standard staining solutions for histologic staining of tissue sections and fungi as iron stain with potassium ferrocyanide and hydrochloric acid (page 134), mucicarmine (page 138), amyloid stain (page 149), silver stain with silver nitrate, sodium hydroxide, and ammonia (page 228), Verhoeff's stain with hematoxylin and ferric chloride (page 240), and silver stain with methanamine and borax. McMannus et al. teach mixing the working solutions of the stains just prior to use from stable stock reagents because the working solutions themselves are unstable for storage over time (see page 134, #2' page 135, #4; page 138, #2; page 240, *Verhoeff's Elastic Tissue Stain*, first paragraph; and page 368, last line of the page).

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have mixed the staining solutions used in the automated method taught by McCormick according to the method disclosed by Copeland et al. in order to fully automate the method of McCormick by eliminating the need for premixing the unstable working stain in a separate step. One of ordinary skill in the art at the time the invention was made would have also found it *prima facie* obvious to have chosen the histologic stains taught by McMannus et al. as suitable for an automated procedure because McMannus et al. teach that they are routinely performed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
Patent Examiner